REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN SUBJECTS

Date: _____

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 1C-116

From: _____

Through:_____
(Signature of Appropriate Official for IC, e.g., Lab/Branch Chief)

Name of NIH Research Investigator(s):_____
_____
IC_____ Laboratory/Branch_____
Building & Room No. _____ Tel. No. _____FAX No. _____

Nature of Research Activity:_____
_____
_____
_____
_____
_____

Associate or Collaborating Investigator(s):

Name Institution Address Tel. # FAX #
_____
_____
_____
_____

Proposed Starting Date of Research Activity:_____

Expected Duration of Research Activity:_____

PLEASE ANSWER ALL THE FOLLOWING QUESTIONS REGARDING THIS RESEARCH ACTIVITY

1. (a) Are you contributing to the design or conduct of the study? Yes/No

   (b) Do you expect your name to appear on a publication resulting from this study? Yes/No

Please describe your role in this research activity:_____
_____
_____
_____
_____

2. Where are the subjects of this research activity located?
_____
_____

3. If the research activity is taking place elsewhere (not at NIH), will you have direct contact or intervention with the human subjects? (Examples: As subject's physician; in obtaining samples directly from the subject; by interviewing the subject?) Yes/No

   Has the activity been reviewed and approved by an Institutional Review Board (IRB) elsewhere? Yes/No

   If "Yes", specify which IRB and when reviewed_____
   _____

4. What kind of human samples (e.g., tissue, blood) or data (e.g., private information, responses to questionnaires) will be involved?_____
   _____
   _____

   Will you be:

   collecting Yes/No
   receiving Yes/No
   sending Yes/No

   these samples or data?

5. Do the samples or data:

   a) Already exist? Yes/No
   b) Or are they being collected for the express purpose of this study? Yes/No
   c) Or a combination of (a) and (b)? Yes/No

   If "Yes", please describe:_____

6. Do the samples or data come from individuals who may need special safeguards (e.g., individuals under 18 years of age, pregnant women, or prisoners)? Yes/No

   If "Yes", please specify_____

7. An IRB must review and approve the use of existing samples or data that are coded and may be linked in any way to an individual, or that contain personal identifiers. The use of samples or data that are anonymous may be considered for exemption from IRB review and approval.

   Are the samples or data you expect to collect, receive or send anonymous? Yes/No
   _____

Please attach separate sheet if there is anything else you wish to add or any answer you wish to amplify. (For further information on exemptions, see the attached "Guidelines for Research Involving Human Subjects")